We Claim:

20

A composition effective for inhibiting the loss of lean body mass in a
 subject under conditions of caloric restriction comprising:

about 8 grams or more of soy protein, and

about 100 micrograms or more of chromium, wherein the chromium is in the form of a biologically acceptable salt or chelate of the chromium.

- 10 2. The composition of claim 1, wherein the composition comprises about 10 grams or more of the soy protein and about 120 micrograms or more of the chromium.
- The composition of claim 2, wherein the composition comprises about
 12 grams or more of the soy protein and about 180 micrograms or more of the chromium.
 - 4. The composition of claim 3, wherein the composition comprises about 12 grams to about 14 grams of the soy protein.
 - 5. The composition of claim 3, wherein the biologically acceptable salt or chelate of the chromium comprises chromium nicotinate or chromium picolinate or compositions thereof.
- 25 6. The composition of claim 5, wherein the composition comprises, in percentage by weight of the total weight of the composition, about 10% to about 50% of the soy protein and about 0.0005% to about 0.10% of the chromium, wherein the biologically acceptable salt or chelate of the chromium comprises chromium nicotinate,

and the composition further comprises, in percentage by weight of the total weight of the composition,

Fructose	about 20% to about 30%
High Oleic Sunflower Oil Powder	about 8% to about 18%
Acacia Gum	about 10% to about 15%
Canola Oil	about 1% to about 5%
Inulin	about 1% to about 5%
Milk Protein Isolate	about 0.5% to about 5%
Dicalcium Phosphate	about 0.5% to about 3%
Silicon Dioxide	about 1% to about 2%
Sodium Citrate	about 0.5% to about 3%
Potassium Chloride	about 0.5% to about 3%
Soy Lecithin	about 0.5% to about 3%
Whey Protein Isolate	about 0.05% to about 2%
Guar Gum	about 0.1% to about 2%
Flavoring	about 1% to about 2%
Vitamin Premix	about 0.05% to about 2%
Mineral Premix	about 0.05% to about 2%
Ferrous Fumarate	about 0.005% to about 0.05%
Sucralose	about 0.001% to about 0.10%
Mixed Tocopherol Concentrate	about 0.0005% to about 0.005%

5 7. The composition of claim 6, wherein the composition comprises, in percentage by weight of the total weight of the composition,

Soy Protein Isolate	about 27.5-29.5%
Fructose	about 23-28%
High Oleic Sunflower Oil Powder	about 11.5-12.75%
Acacia Gum	about 14.5-16%
Canola Oil	about 2-2.75%
Inulin	about 1.75-2.25%
Milk Protein Isolate	about 1.75-2%
Dicalcium Phosphate	about 1.75-2.25%
Silicon Dioxide	about 1-1.75%
Sodium Citrate	about 1-1.25%
Potassium Chloride	about 1-1.25%
Soy Lecithin	about 1-1.10%
Whey Protein Isolate	about 0.9-1%
Guar Gum	about 1.75-2%
Flavoring	about 0.75-1.25%
Vitamin Premix	about 0.4-0.45%
Mineral Premix	about 0.3-0.4%
Chromium Nicotinate	about 0.002-0.004%
Ferrous Fumarate	about 0.020-0.030%
Mixed Tocopherol Concentrate	about 0.001-0.003%

8. The composition of claim 7, wherein the composition further comprises about 0.0080-0.0090% sucralose, and comprises,

Soy Protein Isolate	about 13.91 grams
Fructose	about 11.08 grams
High Oleic Sunflower Oil Powder	about 6.00 grams
Acacia Gum	about 7.50 grams
Canola Oil	about 1.07 grams
Inulin	about 1.00 grams
Milk Protein Isolate	about 0.90 grams
Dicalcium Phosphate	about 0.99 grams
Silicon Dioxide	about 0.80 grams
Sodium Citrate	about 0.58 grams
Potassium Chloride	about 0.57 grams
Soy Lecithin	about 0.50 grams
Whey Protein Isolate	about 0.45 grams
Guar Gum	about 0.90 grams
Flavoring	about 0.37 grams
Vitamin Premix	about 0.21 grams
Mineral Premix	about 0.18 grams
Chromium Nicotinate	about 1.4 milligrams (comprising about
	180 micrograms chromium)
Ferrous Fumarate	about 11.9 milligrams
Sucralose	about 4.0 milligrams
Mixed Tocopherol Concentrate	about 0.9 milligrams

9. The composition of claim 7, wherein the composition comprises,

Soy Protein Isolate	about 13.91 grams
Fructose	about 14.08 grams
High Oleic Sunflower Oil Powder	about 5.90 grams
Acacia Gum	about 7.50 grams
Canola Oil	about 1.10 grams
Inulin	about 1.00 grams
Milk Protein Isolate	about 0.90 grams
Dicalcium Phosphate	about 0.99 grams
Silicon Dioxide	about 0.52 grams
Sodium Citrate	about 0.58 grams
Potassium Chloride	about 0.57 grams
Soy Lecithin	about 0.55 grams
Whey Protein Isolate	about 0.45 grams
Guar Gum	about 0.90 grams
Flavoring	about 0.55 grams
Vitamin Premix	about 0.21 grams
Mineral Premix	about 0.18 grams
Chromium Nicotinate	about 1.4 milligrams (comprising about 180 µg chromium)
Ferrous Fumarate	about 11.9 milligrams
Mixed Tocopherol Concentrate	about 0.9 milligrams

5 10. The composition of claim 5, wherein the composition provides about 100 to about 400 calories.

- 11. The composition of claim 10, wherein the composition provides about 200 calories.
- 12. The composition of claim 5, further comprising an amount of corosolic
 acid effective to inhibit the loss of lean body mass in the subject under caloric restriction.
 - 13. The composition of claim 12, wherein the composition comprises about 0.5-1 mg of corosolic acid.
 - 14. The composition of claim 13, wherein the corosolic acid comprises banaba leaf extract.
- 15. The composition of claim 14, wherein the composition comprises about 5-100 mg of banaba leaf extract.
 - 16. The composition of claim 15, wherein the composition comprises about 25-35 mg of banaba leaf extract.
- 20 17. The composition of claim 13, further comprising an additional 100-600 μg of chromium in the form of a biologically acceptable salt or chelate of the additional chromium.
- 18. The composition of claim 17, further comprising magnesium, zinc, taurine, vanadium, and alpha lipoic acid.
 - 19. A method for losing weight while inhibiting a loss of lean body mass comprising:

10

20

following a calorically restricted diet, and

consuming about 8 grams or more of soy protein per day and about 100 micrograms or more of chromium per day, wherein the chromium is in the form of a biologically acceptable salt or chelate of the chromium, and wherein the amounts of the soy protein and the chromium are effective to inhibit the loss of lean body mass while following the calorically restricted diet.

- 20. The method of claim 19, comprising consuming about 10 grams or more of the soy protein and about 120 micrograms or more of the chromium per day.
- 21. The method of claim 20, comprising consuming about 12 grams or more of the soy protein and about 180 micrograms or more of the chromium per day.
- The method of claim 21, comprising consuming about 12 grams to about 15 14 grams of the soy protein per day.
 - 23. The method of claim 19, wherein consuming the soy protein comprises consuming the soy protein in a shake drink, and wherein consuming the chromium comprises consuming the chromium separately in a pharmaceutically acceptable dosage form.
 - 24. The method of claim 19, wherein the soy protein and the chromium are consumed as a soy protein/chromium composition.
- 25. The method of claim 24, wherein the soy protein/chromium composition provides about 100 to about 400 calories.

- 26. The method of claim 25, wherein the soy protein/chromium composition provides about 200 calories.
- The method of claim 19, comprising following the calorically restricted
 diet and consuming the soy protein and the chromium for a period of about five days or longer.
 - 28. The method of claim 27, comprising following the calorically restricted diet and consuming the soy protein and the chromium for a period of from about 8 weeks to about 12 weeks.
 - 29. The method of claim 28, wherein losing weight includes losing fat mass, and wherein the ratio of lean body mass lost to fat mass lost is less than about 0.6.
- 15 30. The method of claim 19, wherein following the calorically restricted diet comprises consuming 2,000 calories or less per day.
 - 31. The method of claim 30, wherein following the calorically restricted diet comprises consuming 1,400 calories or less per day.
 - 32. The method of claim 31, wherein following the calorically restricted diet comprises consuming 1,200 calories or less per day.
- The method of claim 19, wherein the biologically acceptable salt or
 chelate of the chromium comprises chromium nicotinate or chromium picolinate or
 compositions thereof.

34. The method of claim 24, wherein the soy protein/chromium composition comprises, in percentage by weight of the total weight of the soy protein/chromium composition, about 10% to about 50% of the soy protein and about 0.0005% to about 0.10% of the chromium, wherein the biologically acceptable salt or chelate of the chromium comprises chromium nicotinate, and further comprises, in percentage by weight of the total weight of the soy protein/chromium composition,

Fructose	about 20% to about 30%
High Oleic Sunflower Oil Powder	about 8% to about 18%
Acacia Gum	about 10% to about 15%
Canola Oil	about 1% to about 5%
Inulin	about 1% to about 5%
Milk Protein Isolate	about 0.5% to about 5%
Dicalcium Phosphate	about 0.5% to about 3%
Silicon Dioxide	about 1% to about 2%
Sodium Citrate	about 0.5% to about 3%
Potassium Chloride	about 0.5% to about 3%
Soy Lecithin	about 0.5% to about 3%
Whey Protein Isolate	about 0.05% to about 2%
Guar Gum	about 0.1% to about 2%
Flavoring	about 1% to about 2%
Vitamin Premix	about 0.05% to about 2%
Mineral Premix	about 0.05% to about 2%
Ferrous Fumarate	about 0.005% to about 0.05%
Sucralose	about 0.001% to about 0.10%
Mixed Tocopherol Concentrate	about 0.0005% to about 0.005%

35. The method of claim 34, wherein the soy protein/chromium composition comprises, in percentage by weight of the total weight of the soy protein/chromium composition,

Soy Protein Isolate	about 27.5-29.5%
Fructose	about 23-28%
High Oleic Sunflower Oil Powder	about 11.5-12.75%
Acacia Gum	about 14.5-16%
Canola Oil	about 2-2.75%
Inulin	about 1.75-2.25%
Milk Protein Isolate	about 1.75-2%
Dicalcium Phosphate	about 1.75-2.25%
Silicon Dioxide	about 1-1.75%
Sodium Citrate	about 1-1.25%
Potassium Chloride	about 1-1.25%
Soy Lecithin	about 1-1.10%
Whey Protein Isolate	about 0.9-1%
Guar Gum	about 1.75-2%
Flavoring	about 0.75-1.25%
Vitamin Premix	about 0.4-0.45%
Mineral Premix	about 0.3-0.4%
Chromium Nicotinate	about 0.002-0.004%
Ferrous Fumarate	about 0.020-0.030%
Mixed Tocopherol Concentrate	about 0.001-0.003%

36. The method of claim 35, wherein the soy protein/chromium composition further comprises about 0.0080-0.0090% sucralose, and comprises,

Soy Protein Isolate	about 13.91 grams
Fructose	about 11.08 grams
High Oleic Sunflower Oil Powder	about 6.00 grams
Acacia Gum	about 7.50 grams
Canola Oil	about 1.07 grams
Inulin	about 1.00 grams
Milk Protein Isolate	about 0.90 grams
Dicalcium Phosphate	about 0.99 grams
Silicon Dioxide	about 0.80 grams
Sodium Citrate	about 0.58 grams
Potassium Chloride	about 0.57 grams
Soy Lecithin	about 0.50 grams
Whey Protein Isolate	about 0.45 grams
Guar Gum	about 0.90 grams
Flavoring	about 0.37 grams
Vitamin Premix	about 0.21 grams
Mineral Premix	about 0.18 grams
Chromium Nicotinate	about 1.4 milligrams (comprising about 180 µg chromium)
Ferrous Fumarate	about 11.9 milligrams
Sucralose	about 4.0 milligrams
Mixed Tocopherol Concentrate	about 0.9 milligrams
TOTAL	about 47.31 grams

37. The method of claim 35, wherein the soy protein/chromium composition comprises,

Soy Protein Isolate	about 13.91 grams
Fructose	about 14.08 grams
High Oleic Sunflower Oil Powder	about 5.90 grams
Acacia Gum	about 7.50 grams
Canola Oil	about 1.10 grams
Inulin	about 1.00 grams
Milk Protein Isolate	about 0.90 grams
Dicalcium Phosphate	about 0.99 grams
Silicon Dioxide	about 0.52 grams
Sodium Citrate	about 0.58 grams
Potassium Chloride	about 0.57 grams
Soy Lecithin	about 0.55 grams
Whey Protein Isolate	about 0.45 grams
Guar Gum	about 0.90 grams
Flavoring	about 0.55 grams
Vitamin Premix	about 0.21 grams
Mineral Premix	about 0.18 grams
Chromium Nicotinate	about 1.4 milligrams (comprising about
Ferrous Fumarate	180 μg chromium) about 11.9 milligrams
Mixed Tocopherol Concentrate	about 0.9 milligrams
TOTAL	about 50.19 grams

38. The method of claim 19, further comprising consuming corosolic acid in an amount effective to inhibit the loss of the subject's lean body mass while losing weight under conditions of caloric restriction.

. 25

- 39. The method of claim 38, wherein consuming the corosolic acid comprises consuming about 0.5-1 mg of corosolic acid.
- 40. The method of claim 39, wherein the corosolic acid comprises banaba leaf extract.
 - 41. The method of claim 40, wherein consuming the corosolic acid comprises consuming about 5-100 mg of the banaba leaf extract.
- 10 42. The method of claim 41, wherein consuming the corosolic acid comprises consuming about 25-35 mg of the banaba leaf extract.
 - 43. The method of claim 39, further comprising consuming an additional $100-600 \mu g$ of chromium in the form of a biologically acceptable salt or chelate of the additional chromium.
 - 44. The method of claim 43, further comprising consuming magnesium, zinc, taurine, vanadium, and alpha lipoic acid.
- 20 45. The method of claim 43, wherein the corosolic acid and additional chromium are consumed as a nutritional supplement.
 - 46. The method of claim 45, wherein the nutritional supplement is consumed prior to one or more meals a day.
 - 47. The method of claim 43, further comprising consuming a dietary composition comprising Fucus vesiculosus, Gambogia garcinia, Apis mellifica, Badiaga, Calcarea carbonica, Passiflora incarnata, Baryta carbonica, Calcarea fluorica,

Lycopodium clavatum, Berberis vulgaris, Leptandra virginica, Thuja occidentalis, Galium aparine, Urtica urens, Histaminum muriaticum, and Sabadilla in an amount effective to inhibit the loss of the subject's lean body mass while losing weight under conditions of caloric restriction.

5

- 48. The method of claim 47, wherein the dietary composition is consumed prior to one or more meals a day.
- 49. The method of claim 47, wherein the calorically restricted diet is not consciously followed.
 - 50. A method for treatment of an overweight subject desiring to lose weight comprising:

selecting a subject that is overweight and desires to lose weight, and administering to the subject soy protein and chromium, wherein the chromium is in the form of a biologically acceptable salt or chelate of the chromium, in amounts effective to inhibit the loss of the subject's lean body mass while losing weight under conditions of caloric restriction.

- The method of claim 50, wherein selecting a subject that is overweight comprises selecting a subject having a body mass index of at least about 25.
 - 52. The method of claim 51, wherein selecting a subject that is overweight comprises selecting a subject having a body mass index of at least about 30.

25

15

53. The method of claim 51, wherein selecting a subject that is overweight further comprises selecting a subject with Metabolic Syndrome.

15

- 54. The method of claim 50, further comprising instructing the subject about a calorically restricted diet.
- The method of claim 54, wherein instructing the subject about a
 calorically restricted diet comprises instructing the subject to consume 2,000 calories or less per day.
 - 56. The method of claim 55, wherein instructing the subject about a calorically restricted diet comprises instructing the subject to consume 1,400 calories or less per day.
 - 57. The method of claim 56, wherein instructing the subject about a calorically restricted diet comprises instructing the subject to consume 1,200 calories or less per day.
 - 58. The method of claim 50, wherein losing weight includes losing fat mass, and wherein administering the soy protein and the chromium is effective to result in a ratio of lean body mass lost to fat mass lost of less than about 0.6.
- 20 59. The method of claim 50, comprising administering about 10 grams or more of the soy protein and about 120 micrograms or more of the chromium per day.
 - 60. The method of claim 59, comprising administering about 12 grams or more of the soy protein and about 180 micrograms or more of the chromium per day.
 - 61. The method of claim 60, comprising administering about 12 grams to about 14 grams of the soy protein per day.

62. The method of claim 59, wherein the soy protein comprises administering the soy protein in a shake drink, and wherein administering the chromium comprises administering the chromium separately in a pharmaceutically acceptable chromium dosage form.

5

- 63. The method of claim 59, wherein the soy protein and the chromium are administered as a soy protein/chromium composition.
- 64. The method of claim 63, wherein the soy protein/chromium composition provides about 100 to about 400 calories.
 - 65. The method of claim 50, comprising administering the soy protein and the chromium for a period of at least five days.
 - 66. The method of claim 65, comprising administering the soy protein and the chromium for a period of from about 8 weeks to about 12 weeks.
 - 67. The method of claim 50, wherein the biologically acceptable salt or chelate of the chromium comprises chromium nicotinate or chromium picolinate or combinations thereof.
 - 68. The method of claim 50, further comprising administering corosolic acid to the subject in an amount effective to inhibit the loss of the subject's lean body mass while losing weight under conditions of caloric restriction.

25

15

20

69. The method of claim 68, wherein administering the corosolic acid comprises administering about 0.5-1 mg of corosolic acid.

70. The method of claim 69, further comprising administering to the subject an additional 100-600 μ g of chromium in the form of a biologically acceptable salt or chelate of the additional chromium effective to inhibit the loss of the subject's lean body mass while losing weight under conditions of caloric restriction.

5

15

- 71. The method of claim 70, wherein the corosolic acid and the additional chromium are administered to the subject as a separate nutritional supplement.
- 72. The method of claim 71, wherein the nutritional supplement is administered prior to one or more meals a day.
 - 73. The method of claim 71, further comprising administering to the subject a dietary composition comprising Fucus vesiculosus, Gambogia garcinia, Apis mellifica, Badiaga, Calcarea carbonica, Passiflora incarnata, Baryta carbonica, Calcarea fluorica, Lycopodium clavatum, Berberis vulgaris, Leptandra virginica, Thuja occidentalis, Galium aparine, Urtica urens, Histaminum muriaticum, and Sabadilla in an amount effective to inhibit the loss of the subject's lean body mass while losing weight under conditions of caloric restriction.
- The method of claim 73, wherein the dietary composition is administered prior to one or more meals a day.
 - 75. A kit for inhibiting loss of a subject's lean body mass under conditions of caloric restriction comprising:
- soy protein;

chromium in the form of biologically acceptable salt or chelate of the chromium; and

instructions for consuming amounts of the soy protein and the chromium effective to inhibit the loss of the subject's lean muscle mass under conditions of caloric restriction.

- 5 76. The kit of claim 75, wherein the biologically acceptable salt or chelate of the chromium comprises chromium nicotinate or chromium picolinate or compositions thereof.
- 77. The kit of claim 76, wherein the instructions instruct the subject to consume about 12 grams or more of the soy protein per day.
 - 78. The kit of claim 77, wherein the instructions instruct the subject to consume about 120 micrograms or more of the chromium per day.
 - 79. The kit of claim 78, wherein the instructions instruct the subject to consume about 180 micrograms or more of the chromium per day.
 - 80. The kit of claim 79, wherein the instruction further instruct the subject to consume about 1800 kcal/day or less.

O1 The left of claims 70 whomein the resummatein

81. The kit of claim 78, wherein the soy protein and chromium are provided in one or more doses of 12 grams or more of the soy protein and 120 grams or more of the chromium and the instructions instruct the subject to consume one or more of the doses of the soy protein and the chromium per day.

25

15

20

82. The kit of claim 81, wherein each dose of the soy protein and the chromium is provided in a soy protein/chromium composition comprising the soy protein and the chromium.

EXPRESS MAIL LABEL NO. EV339203435US DATE OF DEPOSIT: November 24, 2003

- 57 -

83. The kit of claim 82, further comprising corosolic acid and instructions for consuming the corosolic acid in an amount effective to inhibit the loss of the subject's lean muscle mass under conditions of caloric restriction.

5

- 84. The kit of claim 83, wherein the corosolic acid is provided in one or more doses of a nutritional supplement comprising about 0.5-1 mg of the corosolic acid.
- 85. The kit of claim 84, wherein the nutritional supplement further
 comprises 100-600 μg of additional chromium in the form of a biologically acceptable
 salt or chelate of the additional chromium effective to inhibit the loss of the subject's
 lean muscle mass under conditions of caloric restriction.
- 86. The method of claim 85, wherein the instructions instruct the subject to consume the nutritional supplement prior to one or more meals a day.
 - 87. The kit of claim 83, further comprising a dietary composition comprising Fucus vesiculosus, Gambogia garcinia, Apis mellifica, Badiaga, Calcarea carbonica, Passiflora incarnata, Baryta carbonica, Calcarea fluorica, Lycopodium clavatum, Berberis vulgaris, Leptandra virginica, Thuja occidentalis, Galium aparine, Urtica urens, Histaminum muriaticum, and Sabadilla and instructions for consuming the dietary supplement acid in an amount effective to inhibit the loss of the subject's lean muscle mass under conditions of caloric restriction.
- 25 88. The kit of claim 87, wherein the instructions instruct the subject to consume the dietary composition prior to one or more meals a day.